

WHAT IS CLAIMED IS:

1. A pharmaceutical composition for the treatment of a disorder caused by the abnormal dissolution or deposition of calcium salts comprising:

an inert core,
an active coating surrounding the inert core,
a seal coating surrounding the active coating,
and an enteric coating around said seal coating;

wherein the active coating comprises at least one bisphosphonic acid or salt thereof.

2. The composition according to claim 1, wherein the at least one bisphosphonic acid is selected from the group consisting of:

4-Amino-1-hydroxybutylidene-1,1-bisphosphonic acid;
N-Methyl-4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid;
4-(N,N-Dimethylamino)-1-hydroxybutylidene-1,1-bisphosphonic acid;
3-Amino-1-hydroxypropylidene-1,1-bisphosphonic acid;
3-(N,N-Dimethylamino)-1-hydroxypropylidene-1,1-bisphosphonic acid;
1-Hydroxy-3-(N-methyl-N-pentylamino)propylidene-1,1-bisphosphonic acid;
4-(Hydroxymethylene-1,1-bisphosphonic acid)-piperidine; and
salts thereof.

3. The composition according to claim 1, wherein the at least one bisphosphonic acid is alendronic acid.

4. The composition according to claim 1, wherein the at least one bisphosphonic acid or salt thereof is selected from the group consisting of

alendronate sodium trihydrate, etidronate, clodronate, pamidronate, and ibandronate.

5. The composition according to claim 1, wherein the composition comprises from about 4% to about 40% by weight of the at least one bisphosphonic acid or salt thereof.

6. The composition according to claim 1, wherein the seal coating comprises one or more hydrophilic polymers selected from the group consisting of hydroxypropyl methylcellulose, hydroxypropyl cellulose, polyvinyl pyrrolidone, shellac, cellulose gum and xanthan gum.

7. The composition according to claim 1, wherein the enteric coating is selected from the group consisting of hydroxypropyl methylcellulose phthalate, hydroxypropyl cellulose acetyl succinate, cellulose acetate phthalate, polyvinyl acetate phthalate, methacrylic acid-methyl methacrylate copolymers, and mixtures thereof.

8. The composition according to claim 7, wherein the methacrylic acid-methyl methacrylate copolymer is selected from the group consisting of Eudragit L 12.5, Eudragit L 100 55, Eudagrit S 100 and mixtures thereof.

9. The composition according to claim 1, wherein the inert core comprises sugar beads or sugar/starch beads.

10. The composition according to claim 1, wherein the active coating further comprises at least one of a solubilizer and a lubricant.
11. The composition according to claim 1, wherein the active coating comprises a polymer film comprising a mixture of at least one bisphosphonic acid or salt thereof and a polymer.
12. The composition according to claim 11, wherein the polymer is selected from the group consisting of hydroxypropyl methylcellulose, hydroxypropyl cellulose and polyvinyl pyrrolidone.
13. The composition according to claim 1, further comprising a binder.
14. A capsule or Peltab comprising a plurality of pellets each of which comprises a composition according to claim 1.
15. The composition according to claim 1, wherein the composition releases the at least one bisphosphonic acid or salt thereof only in the lower gastrointestinal tract of a human or animal upon ingestion.
16. The composition according to claim 1, wherein the disorder caused by the abnormal dissolution or deposition of calcium salts is selected from the group consisting of osteoporosis, osteodystrophy, Paget's disease, myositis ossificans,

Bechterew's disease, cholelithiasis, nephrolithiasis, urinary calculus, arteriosclerosis, arthritis, bursitis, neuritis and tetany.

17. The capsule or Peltab of claim 14, further comprising an enteric coating over said capsule or Peltab.

18. A method for treating a disorder caused by the abnormal dissolution or deposition of calcium salts comprising:

providing a pharmaceutical composition; and

administering an effective dose of the pharmaceutical composition to a person in need thereof;

wherein the pharmaceutical composition comprises an inert core, an active coating surrounding the inert core, a seal coating surrounding the active coating, and an enteric coating around said seal coating; and wherein the active coating comprises at least one bisphosphonic acid or salt thereof.

19. The method according to claim 18 wherein the at least one bisphosphonic acid is selected from the group consisting of:

4-Amino-1-hydroxybutylidene-1,1-bisphosphonic acid;

N-Methyl-4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid;

4-(N,N-Dimethylamino)-1-hydroxybutylidene-1,1-bisphosphonic acid;

3-Amino-1-hydroxypropylidene-1,1-bisphosphonic acid;

3-(N,N-Dimethylamino)-1-hydroxypropylidene-1,1-bisphosphonic acid;

1-Hydroxy-3-(N-methyl-N-pentylamino)propylidene-1,1-bisphosphonic acid;

4-(Hydroxymethylene-1,1-bisphosphonic acid)-piperidine; and salts thereof.

20. The method according to claim 18, wherein the at least one bisphosphonic acid is alendronic acid.

21. The method according to claim 18, wherein the at least one bisphosphonic acid salt is selected from the group consisting of alendronate sodium trihydrate, etidronate, clodronate, pamidronate, and ibandronate.

22. The method according to claim 18, wherein the disorder caused by the renal dissolution or deposition of calcium salts is selected from the group consisting of osteoporosis, osteodystrophy, Paget's disease, myositis ossificans, Bechterew's disease, cholelithiasis, nephrolithiasis, urinary calculus, arteriosclerosis, arthritis, bursitis, neuritis and tetany.